OCT - 5 2001

K003431

Premarket Notification 510(k) Safety and Effectiveness Summary

ZEUS® Robotic Surgical System 510(k) Summary

In accordance with 21 CFR section 807.92 Computer Motion is submitting the following safety and effectiveness summary.

1) Submitter Information

Computer Motion. Inc.
130-B Cremona Drive
Goleta, CA 93117

Contact: David U. Thomas
Prepared: October 4, 2001

2) Name of Device:

Proprietary Name: ZEUS® Robotic Surgical System
Common Name is ZEUS System
Classification Name: Laparoscope for Use in General and Plastic Surgery, Regulation Number 876.1500, Class II.

3) Substantially equivalent to Intuitive Surgical™ Endoscope Instrument Control System (K965001)

4) The ZEUS® Robotic Surgical System is intended to assist in the accurate control of blunt dissectors, retractors, atraumatic graspers and stabilizers during laparoscopic and thoracoscopic surgery.

The users of the ZEUS® Robotic Surgical System are surgeons trained in minimally invasive surgery. Assistant surgeons can also use this system while under the direction of the primary surgeon in accordance with hospital's customary practice.

5) The ZEUS® System is designed and tested to the following Computer Motion and voluntary standards.

IEC 601-1 Second Edition 1990 International Standard for Medical Electrical Equipment
IEC 601-1 Amendment 1 1991 International Standard for Medical Electrical Equipment
IEC 601-2-18 First Edition 1990 International Standard for Medical Electrical Equipment
UL 2601-1
Conducted & Radiated Emission EN55022/A1: 1995
Immunity Tests EN61000-4-2: 1995; EN61000-4-3: 1995; EN50140:1994; EN61000-4-4:1995; EN61000-4-5:1995; EN61000-4-6:1995.
CAN/CSA-C22.2 NO. 601.1-M90 & NO. 601.2.18-92

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 5 2001

Mr. David U. Thomas
Regulatory Affairs Specialist
Computermotion, Inc.
130 Cremona Drive
Santa Barbara, California 93117

Re: K003431
Trade/Device Name: ZEUS® Robotic Surgical System
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: July 11, 2001
Received: July 12, 2001

Dear Mr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walk, MS

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003431

Device Name: ZEUS® Robotic Surgical System

Indication For Use:

The ZEUS® Robotic Surgical System is intended to assist in the accurate control of blunt dissectors, retractors, atraumatic graspers and stabilizers during laparoscopic and thoracoscopic surgery.

The users of the ZEUS® Robotic Surgical System are surgeons trained in minimally invasive surgery. Assistant surgeons can also use this system while under the direction of the primary surgeon in accordance with hospital's customary practice.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003431